PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Applicant's or agent's file reference see form PCT/ISA/220	Date of mailing *(day/month/year)* see form PCT/ISA/210 (second sheet) **FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IL2007/001588	20.12.2007	20.12.2006

International Patent Classification (IPC) or both national classification and IPC
INV. G06F17/30 G06T7/00 G06F19/00

Applicant
SPECTRUM DYNAMICS LLC

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:	Date of completion of this opinion	Authorized Officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89.2399 -.4465	see form PCT/ISA/210	Krawczyk, Grzegorz Telephone No. +49 89 2399-5956

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
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Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ on paper

   ☐ in electronic form

   c. time of filing/furnishing:

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in electronic form.

   ☐ furnished subsequently to this Authority for the purposes of search.

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

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Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has, within the applicable time limit:

   ☐ paid additional fees

   ☐ paid additional fees under protest and, where applicable, the protest fee

   ☐ paid additional fees under protest but the applicable protest fee was not paid

   ☒ not paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

   see separate sheet

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-27,37-47

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	7, 8, 11-14, 16, 18, 42
	No:	Claims	1-6, 9, 10, 15, 17, 19-27, 37-41, 43-47
Inventive step (IS)	Yes:	Claims	
	No:	Claims	7, 8, 11-14, 16, 18, 42
Industrial applicability (IA)	Yes:	Claims	1-27,37-47
	No:	Claims	

2. Citations and explanations

see separate sheet

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item IV.

The application appears to lack unity within the meaning of Rule 13.1 PCT, since it does not seem to relate to one invention only or to a group of inventions so linked as to form a single general inventive concept.

In fact, claims **1**, **19** and **23** have been drafted as roof-type claims with a general concept defined in lines 3-8 of claim **1** and three alternatives specified at the end of claim **1**. With these alternatives, claim **1** effectively separates into three independent claims, directed to using the "matching set" for image acquisition, diagnosis and classification respectively. The latter two issues, diagnosis and classification, seem to be closely related, whereas image acquisition solves a different technical problem and requires an extra search.

Therefore, the application is considered to contain the following two separate inventions:

1) Claims: **1-27** and **37-47**.

The first invention refers to a method (claim **1**), a system (claim **19**), and a distributed system (claim **23**) for analysing a received functional map. The same invention is further defined using different wording as a research tool (claim **24**) and a method for calculating a treatment recommendation (claim **37**).

The purpose of the first group of inventions is to mine a database of functional maps for diagnosis and classification.

2) Claims: **28-36**.

The second invention refers to an imaging system (claim **28**) and a method for obtaining a functional image (claim **33**) in which the process of capturing (and a corresponding "detector" in a system) is controlled based on the analysis of a preliminary functional image (map).

The technical problem solved here is to improve the quality of a captured medical image.

As noted above, there is in fact a single general concept with the following features common to both inventions:

- "receiving a functional map" (obtaining an input image),
- "managing a plurality of functional maps associated with biological activity indications" (i.e. providing a database of functional maps),
- "identifying a matching set of said managed functional maps by matching between (...) biological activity indications".

These features are, however, known from document US 2004/0003001 (**D1**) which is cited in the search report. This document discloses a system for searching for similar images in a database containing medical images and associated medical information (cf. par. [0012,18] in D1), wherein the search is based on image content or associated medical information. Thus, regarding document **D1**, the single general concept linking the two invention appears to be not new and not inventive within the meaning of Article 33 PCT. Furthermore, the two technical problems of the abovementioned inventions are solved by different and not corresponding special technical features.

Re Item V.

1. Reference is made to the following documents:

   D1: US 2004/003001 A1 (SHIMURA KAZUO [JP]) 1 January 2004
   D2: WO 2006/042077 A (VIATRONIX INC [US]) 20 April 2006

2. The method claims **1** and **37** are construed as pure mental acts and as such do not meet the requirements of Rule 39.1(iii) PCT. Since this deficiency can be easily overcome by rewording the claims to "computer implemented method", further comments and objections are made assuming such an implementation of these methods.

3. Comments and objections regarding independent claims.

3.1. Document **D1** discloses, in the context of medical images, a method for analysing a

functional map of at least one tissue of a patient (cf. par. [0051] in D1, further references are made to D1; note that a diagnosis is assumed to be an equivalent of analysis, an "image" falls withing the meaning of a "functional map" as supported by the description, and that a "medical image" may be a record of a tissue of a patient), comprising:

- managing a plurality of functional maps each being associated with a plurality of first biological activity indications (cf. par. [0012,14]; note that a medical image and a description thereof implicitly contain biological activity indications);
- receiving a functional map being associated with a plurality of second biological activity indications (cf. par. [0012]);
- identifying a matching set of said managed functional maps by matching between said plurality of first and second biological activity indications (cf. par. [0014]); and
- using said matching set for a member of a group consisting of: an image data acquisition, a diagnosis of said received functional map, a classification of said received functional map (cf. par. [0051] regarding diagnosis and classification).

Hence, the subject-matter of claim **1** is not novel (Article 33(2) PCT).

3.2. Claim **19** defines a system for performing the method steps of claim **1** and as such is not novel (Article 33(2) PCT) for the reasons stated in point 3.1.

3.3. Claim **23** defines a distributed system for performing the method steps of claim **1** which further comprises a plurality of terminals. Such a system is known from **D1** (cf. par. [0030]), therefore claim **23** is also not novel (Article 33(2) PCT).

3.4. Claim **24** defines a "research tool" for identifying a trial group based on patient profiles. In view of the description, a trial group is understood to be an equivalent of the "matching set". Since the similarity search based on a patient profile is known from **D1** (cf. par. [0032]), claim **24** is not novel (Article 33(2) PCT).

3.5. The same objections as above could also be raised with respect to document **D2**. **D2** discloses a library of medical images associated with pathological, histological, and diagnosis information, and a use of such a library for analysing a received medical

image based on similar images found in the library (cf. p.2,22 in D2).

3.6. Claim **37** defines a method for calculating a treatment recommendation based on patient profiles with similar steps as in claim **1**, but not limited to functional maps or images. Hence, claim **37** is even broader than claim **1**. In fact, claim **37** is directed to data retrieval starting from generic patient profiles. For that reason, one could have formally raised a further non-unity objection. As the case may be, claim **37** nevertheless lacks novelty in view of document **D1** (Article 33(2) PCT), since the same procedure is discussed in **D1** (cf. par. [0009,25]) including the fact of using patient profiles (cf. par. [0018-19,32] in D1).

4. Comments and objections regarding dependent claims.

According to the reasoning outlined below,

- claims **2-6**, **9**, **10**, **15**, **17**, **20-22**, **25-27**, **38-41**, **43-47** are considered to be not novel (Article 33(2) PCT),
- claims **7**, **8**, **11-14**, **16**, **18** and **42** seem to be novel but do not appear to involve an inventive step (Article 33(3) PCT),
- no claim has been found novel and inventive.

4.1. Claims **2-4**, **6**, **9**, **10**, **15**, **17**, **25-27**, **38-41**, **43** and **44** focus on contents and define further details regarding functional maps and matching. Technically, these details do not go beyond the disclosure of **D1**. Claim **15** discloses additionally a use for treatment recommendation and claim **17** a use for classification, both can also be found in **D1** (cf. par. [0051,65]).

4.2. Claims **5** and **20** define registering, denoising, and converting data format of functional maps before matching which as such is not disclosed in **D1**. Such a preprocessing is, however, known from **D2** (cf. p.12 lines 15-18), where it is disclosed in the same technical context (cf. p.2 lines 7-20 in D2).

4.3. Claims **7**, **8**, **11**, **14** and **42** focus on content of the functional maps and do not appear to contain any technically relevant limitation with respect to claim **1**.

4.4. Claims **12**, **13** and **16** specify details on matching which is based on topology or on pattern matching and as such do not add anything inventive with regard to document **D1** (cf. par. [0014]).

4.5. Claim **18**: the mere statement of performing the method of claim **1** in real time is not inventive.

4.6. Claims **21** and **22**: a display unit and a feature of weighting the results according to relevance can also be found in **D1** (cf. par. [0051]).

4.7. Claims **45-47** refer to updating the database information with the new data on ongoing treatment. Such reinforcing of a database is also disclosed in **D1** (cf. par. [0035]).

5. The following formal deficiencies have been observed in the application.

5.1. Document **D1** is not acknowledged as prior art in the description.

Re Item VIII.

The present set of independent claims lacks conciseness (Article 6 PCT).

Claims **1**, **19** and **23** refer to a method for analysing functional maps (images) together with a related system and a distributed system, and are largely equivalent. On the other hand, claims **24** and **37** are much broader because they refer to analysis of generic data - patient profiles. For that reason, the scope for which the protection is sought is not clearly defined.

Possible steps after receipt of the international search report (ISR) and written opinion of the International Searching Authority (WO-ISA)

General information	For all international applications filed on or after 01/01/2004 the competent ISA will establish an ISR. It is accompanied by the WO-ISA. Unlike the former written opinion of the IPEA (Rule 66.2 PCT), the WO-ISA is not meant to be responded to, but to be taken into consideration for further procedural steps. This document explains about the possibilities.
Amending claims under Art. 19 PCT	Within 2 months after the date of mailing of the ISR and the WO-ISA the applicant may file amended claims under Art. 19 PCT directly with the International Bureau of WIPO. The PCT reform of 2004 did not change this procedure. For further information please see Rule 46 PCT as well as form PCT/ISA/220 and the corresponding Notes to form PCT/ISA/220.
Filing a demand for international preliminary examination	In principle, the WO-ISA will be considered as the written opinion of the IPEA. This should, in many cases, make it unnecessary to file a demand for international preliminary examination. If the applicant nevertheless wishes to file a demand this must be done before expiry of 3 months after the date of mailing of the ISR/WO-ISA or 22 months after priority date, whichever expires later (Rule 54bis PCT). Amendments under Art. 34 PCT can be filed with the IPEA as before, normally at the same time as filing the demand (Rule 66.1 (b) PCT). If a demand for international preliminary examination is filed and no comments/amendments have been received the WO-ISA will be transformed by the IPEA into an IPRP (International Preliminary Report on Patentability) which would merely reflect the content of the WO-ISA. The demand can still be withdrawn (Art. 37 PCT).
Filing informal comments	After receipt of the ISR/WO-ISA the applicant may file informal comments on the WO-ISA directly with the International Bureau of WIPO. These will be communicated to the designated Offices together with the IPRP (International Preliminary Report on Patentability) at 30 months from the priority date. Please also refer to the next box.
End of the international phase	At the end of the international phase the International Bureau of WIPO will transform the WO-ISA or, if a demand was filed, the written opinion of the IPEA into the IPRP, which will then be transmitted together with possible informal comments to the designated Offices. The IPRP replaces the former IPER (international preliminary examination report).
Relevant PCT Rules and more information	Rule 43 PCT, Rule 43bis PCT, Rule 44 PCT, Rule 44bis PCT, PCT Newsletter 12/2003, OJ 11/2003, OJ 12/2003